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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,997	02/05/2004	Kjell Malmlof	5904.214-US	5384

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,997	MALMLOF ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-11,14,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-11,14,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *NA* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/140,512.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/22/05*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response of 04/13/2006 is acknowledged. The Examiner's indication of allowable subject matter in the previous Office Action (12/15/2005) has been removed, in view of a new rejection of record (35 USC 112 1st). Likewise, in view of the new rejection, the present Office Action is being sent NON-FINAL. Claims 1-6, 8-11, 14, and 19-20 are examined on the merits.

Objection: Specification/Drawings

The specification/drawings are objected to for the following reason(s): The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). It appears the parent application, to which this application depends (10/140,512) contains Figures 1-6, and should be expressly filed with this application as well, in a supplement.

Claim Rejections - 35 U.S.C. § 112 1st Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-11, 14, and 19-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (unclaimed) a method for treatment of obesity using growth hormone (GH) (known in the art though, see e.g. US 4,863,901, entire document); does not reasonably provide enablement for a method for "suppressing appetite in a mature human patient comprising GH by injection". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for a method for "suppressing appetite in a mature human patient comprising GH by injection" for the following reasons:

The nature of the invention: The claimed invention is discussed above.

The state of the prior art and the predictability or lack thereof in the art:

In a literature review of the appetite effect of GH on various species, the conclusions are inconclusive (Wang et al., J. of Endrocrinology, 2000, 166, 621-630). "*Among the many responses to GH administration is suppression of voluntary feed intake (FI) in some species . . .*" (abstract). "*Numerous investigators have demonstrated that GH alters voluntary feed intake (FI), but there are marked species differences (first para.).*

For instance, [contrary to Applicants studies on rats,] GH has been shown to *increase appetite* in *rats* (Azain et al., 1995, cited therein).

While, GH has been show to have a *suppress appetite* in:
1. broiler chickens;
2. pigs (Klindt et al., 1998); and
3. anorexic/bulimic patients during the binge-eating cycle of elevated food consumption (Vaccarino et al., 1994; although abstract of article appeared to indicate that growth hormone releasing factor (GRF) increased appetite in anorexic patients, and assumedly increased GH therewith).

Thus, absent specific species testing, and possibly other factors, there does not appear to be a clear animal model for human testing, other than conducting tests directly on humans (which has been done in at least one subpopulation (anorexic/bulimic patients) with mixed results (see above).

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The specification clearly describes that GH is useful for the known use of treating obesity. However, in terms of the claimed invention (discussed above and only drawn to human treatment), the specification only describes mixed results of GH on appetite suppression (without any reference to sources, but indicating the same findings discussed above under 'prior art', which does cite reference sources) (see specification

page 2, lines 18-26). Furthermore, Applicant has only tested GH for suppressing/increasing appetite/food intake, as to obese rats (see Fig. 1, parent application), with no clear indication of what amount constitutes the "appetite suppression effective amount" even in normal rats versus obese rats, or what such amount would be necessary in normal versus obese humans. [Note: As GH has been tested routinely on humans in the past, it is unclear to the Examiner, with the prior art teachings as to mixed results/unpredictability of GH on appetite/food intake amongst various species and even within species themselves (see Applicant's specification page 2 description), why Applicant himself did not once again test GH in the human species (or subpopulations therein, e.g. obese humans) to which all the claims are directed; as other researchers have conducted GH studies on the species of interest? Should Applicant have later done this, it is suggested that such data be presented in the form of an Affidavit/Declaration if deemed useful to the enablement of the presently claimed invention.]

The breadth of the claims and the quantity of experimentation needed: The claims are drawn broadly to a method for "suppressing appetite in a mature human patient comprising GH by injection". Absent sufficient teachings in the specification or art sufficient to overcome the teachings of unpredictability in the art as to enablement on whether GH can suppress appetite in any human species or subpopulation therein; it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 09/15/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654